APR 2 7 2005

K050508

Haywood Vocational Opportunities, Inc.
Various Disposable Non-Sterile Surgical Drapes

510(k) Summary

Summary of the Safety and Effectiveness Information Upon Which An Equivalence Could Be Based

SPONSOR INFORMATION

Name: Haywood Vocational Opportunities, Inc.
Address: P.O. Box 7
Hazelwood, N.C. 28738
Telephone: (828) 456-4455
Fax: (828) 456-4401

DEVICE NAMES

Name: HVO, Inc., Various Disposable Non-Sterile Surgical Drapes
Common/Usual Name: Surgical Drapes
Classifications Name (if known): Surgical and Drape Accessories
Device Names: Table Covers, OB GYN, General Surgery, Orthopedic, ENT and EENT, Drape Sheets, Cystoscopy, Craniotomy, Angiography, Fluid Pouches, and Instrument Covers.

PREDICATE OR LEGALLY MARKETED DEVICES

There are several predicate devices currently on the market that have similar function and are made from same or similar materials.

DEVICE DESCRIPTION

The proposed HVO, Inc. Various Disposable Non-Sterile Surgical Drapes function in the same manner as predicate devices in that they are intended to be used as protective patient coverings, such as used to isolate a site of surgical incision from microbial and other contamination.

Device Design/ Materials Used/ Physical Properties: The HVO, Inc. Various Disposable Non-Sterile Surgical Drapes are made of materials commonly used for their purpose. The primary material components are SMS, Micro-embossed LDPE, Clear LDPE, Nonwoven (wetlaid cellulose), Airtex, Sontara, Krayton, Medical Grade Single and Double Coated Tapes, Bridging, Polyfoam, Velcro, Polyester Mesh, Hot Melt, Cold Glue and Coated Medical Grade Liners.

Primarily all of our drapes are offered in the color blue, which is the common color for medical device materials, but some materials are offered in white or with white backing. These materials include Nonwovens, SMS, Airtex, Sontara, Polyfoam, Back Table Covers, Bridging, and LDPE's. All other materials are clear plastics or adhesives, which are not colored, but natural.

DEVICE INTENDED USE

The HVO, Inc. Various Non-Sterile Surgical Drapes are intended to be used as protective patient covering, such as to isolate surgical incisions from microbial and other contamination. These proposed devices are intended to undergo sterilization by the customer prior to use in the sterile setting. These products can be sterilized by ETO. The products may be sterilized using Ethylene Oxide following the Validation and Routine Control under ANSI/AAMI/ISO 11135, see **section 12** for more details on **sterilization**.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICE(S)

Characteristics	**HVO, Inc. Devices**	**Other Devices**
Materials	SMS, Micro-Embossed LDPE, Clear LDPE, Sontara, Nonwoven, Krayton, Airtex, Polyfoam, Medical Grade Single And Double Coated Tapes, Velcro, Cold Glue, Hot Melt, Bridging, Polyester Mesh Coated Medical Grade Liners	Same or similar materials
Absorbency	Absorbent and Non-Absorbent	Same
Packaging	Bulk and Single Use	Bulk and Single Use
Disposable	Yes	Yes
Sterility	Non-Sterile	Non-Sterile and Sterile

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2005

Mr. Tim Kelley
Director of Regulatory Affairs
Haywood Vocational Opportunities, Incorporated
56 Scates Street
Waynesville, North Carolina 28786

Re: K050508
Trade/Device Name: Various Disposable Non-Sterile Surgical Drapes (Table Covers, OB GYN, General Surgery, Orthopedic, ENT and ENNT, Drape Sheets, Cystoscopy, Craniotomy, Angiography, Fluid Pouches, and Instrument Covers)
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: April 19, 2005
Received: April 20, 2005

Dear Mr. Kelley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

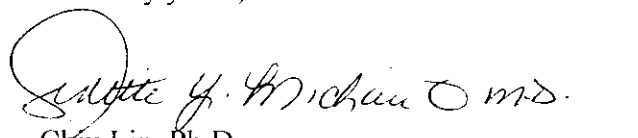
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K050508

Device Name: HVO, Inc. Various Disposable Non-Sterile Surgical Drapes
(Table Covers, OB GYN, General Surgery, Orthopedic, ENT and ENNT, Drape Sheets, Cystoscopy, Craniotomy, Angiography, Fluid Pouches, and Instrument Covers).

Indications For Use:

HVO surgical drapes are made from natural and synthetic materials intended to be used by medical professionals as protective coverings, such as a patient covering to isolate a site for surgical incision from contamination. They are designed to be repackaged and/or sterilized before use.

This single use product is a disposable non-sterile drape designed to be re-packaged and/or sterilized prior to use. This product may be sterilized using Ethylene Oxide (EO) following the Validation and Routine Control under ANSI/AMMI/ISO 11135. For more information about sterilization of this product, contact HVO, Inc.

Prescription Use__X___ and/or Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Linda A. Murphy

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K050508